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Filed : **November 21, 2003**

REMARKS

Claims 1-54 were pending prior to entry of these amendments. Claims 1, 4, 5, 8, 9 18, 31, 42, 47, and 52 are amended herein. Claims 2, 3, 7, 11, 12, 27, and 41 are canceled herein.

Drawings

The drawings are objected to under 37 C.F.R. §1.83(a) for not showing certain features. To overcome this rejection, Claims 11, 12, 27, and 41 have been canceled to cancel those features from the claims. The reference to “a plurality of valves” has been deleted from Claim 52.

Rejections Under 35 U.S.C. §112

Claims 11 and 12 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully submit that Claims 11 and 12 are fully supported by the specification as originally filed at, for example, paragraph [0042].

Rejections Under 35 U.S.C. §102

Claims 1-10, 13-28, 31-39, 41, and 47-54 are rejected under 35 U.S.C. §102(e) as being anticipated by Nobles et al., US 2002/0013601 A1. Claims 1, 2, 7, 18, 20-26, and 42-49 are rejected under 35 U.S.C. §102(b) as being anticipated by Ghodsian, U.S. Patent No. 4,664,114. Claim 1 has been amended to recite an anchoring feature to anchor the device within the cervical canal, wherein the anchoring feature is an uneven outer surface of the expandable mechanism when it is expanded. Claim 9 has been amended similarly to recite radially expanding the at least one expandable dilator within the canal to dilate the cervical canal while the tube is in the canal, wherein the at least one expandable dilator has an uneven outer surface. Claim 18 has been amended to recite a second expandable component attached to the elongated member proximally of the first expandable component, wherein the second expandable component has an uneven outer surface. Claim 31 has been amended to recite an expandable seal assembly attached to the elongated member, wherein the seal assembly has an uneven outer surface in an expanded condition. Claim 42 has been amended to recite a second expandable component attached to the elongated member proximally of the first expandable component, wherein the second expandable

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component has an uneven outer surface. Claim 47 has been amended to recite that the seal assembly has an uneven outer surface when it is expanded. Claim 52 has been amended to recite that the balloon has an uneven outer surface when inflated. These amendments are fully supported by the specification as originally filed, at, for example, paragraph [0053] and Figure 3A. Claims 2, 3, and 7 have been canceled. Claims 4, 5, and 8 have been amended to depend from a non-canceled claim.

Nobles et al. do not disclose or suggest an anchoring feature that is an uneven outer surface of the expandable mechanism when it is expanded, as recited in amended Claim 1. Nor do Nobles et al. disclose or suggest radially expanding an expandable dilator within the cervical canal to dilate the canal, wherein the dilator has an uneven outer surface, as recited in amended Claim 9, a second expandable component having an uneven outer surface, as recited in amended Claim 18, nor a seal assembly having an uneven outer surface, as recited in amended Claims 31 and 47, nor a balloon having an uneven outer surface as recited in amended Claim 52.

Nobles et al. disclose first and second distending members 418, 420 spaced apart and connected by a tubular connector 422. The first distending member 418 is configured to conform to the proximal opening of the cervix and the second distending member 420 is configured to conform to the distal opening of the cervix. *See* Nobles et al. at paragraph [0084]. In Nobles et al., none of the first distending member 418, second distending member 420, and the tubular connector 422 has an uneven outer surface.

With reference to Figure 8A, Nobles et al. also disclose an embodiment of a balloon 812 comprising first and second distending members 104, 106 and a tubular connector 108 comprising a plurality of distending members 814. Although the distending members have different diameters, the distending members 814 do not define an uneven *outer* surface of an expandable mechanism or dilator, as claimed. As discussed in paragraph [0106] of Nobles et al., the *outer* layer of the balloon 812 is not shown in Figure 8A.

As with the embodiment discussed above, in the embodiment of FIG. 8A, it is contemplated that the distending members 104, 106 and the intermediate distending members 814 are made of a single, continuous one-piece balloon member that provides at least one interior inflatable chamber. An annular seal 110' may be formed between the tubular connector 108 and the second distending member 106, and an annular seal 110 may be formed between the tubular connector 108 and the first distending member 104. Similarly, each intermediate distending

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member 814 may have a proximal annular seal 816 and a distal annular seal 816' to isolate a chamber therebetween. The annular seals 110, 110', 816, 816' are formed circumferentially *between inner and outer layers (not shown)* of the balloon 812 using radio frequency (RF) welding, ultrasound welding, thermal bonding, adhesive, or other suitable techniques.

Nobles et al. at paragraph [0106] (emphasis added). Thus, the uneven surface shown in Figure 8A is not the *outer* surface of the balloon 812. Claims 1, 9, 18, 31, 47, and 52, as amended, are therefore not anticipated by Nobles et al. For example, the distending members 814 do not engage with the cavity being dilated and therefore are not an *anchoring* feature that is an uneven *outer* surface of the expandable mechanism, as recited in amended Claim 1, nor a dilator, as recited in amended Claim 9. The distending members 814 of the Nobles et al. balloon are therefore part of the underlying structure of the balloon 812 and are not part of the *outer* surface of the balloon 812. As noted above, Claims 1, 9, 18, 31, 47, and 52, as amended, are patentable as they are not anticipated by Nobles et al. Claims 2-8, 10, 13-17, 19-28, 32-39, 41, 48-51, and 53-54, which depend from and include all of the limitations of Claim 1, 9, 18, 31, 47, or 52, are therefore also patentable over Nobles et al. Furthermore, each of the dependent claims recites further distinguishing features of particular utility.

Similarly, Ghodsian does not disclose or suggest an *uneven outer surface* of an expandable mechanism or component, as recited in amended Claims 1, 18, 42, and 47. In Ghodsian, the expandable mechanisms 13, 14 do not have an uneven outer surface. As shown in Fig. 1, the two expandable mechanisms 13, 14 have smooth outer surfaces. Furthermore, Ghodsian teaches that the first expandable mechanism 13 is inflated within the *uterine cavity* and acts as an anchoring device in the inflated state. Thus, Ghodsian does not provide any suggestion for an *anchoring feature to anchor the device within the cervical canal*, wherein the anchoring feature is an uneven outer surface of the expandable mechanism when it is expanded, as recited in amended Claim 1. Amended Claims 1, 18, 42, and 47 are therefore patentable as they are not anticipated by Ghodsian. Claims 2, 7, 20-26, and 43-49, which depend from and include all of the limitations of Claim 1, 18, 42, or 47, are also patentable over Ghodsian. Furthermore, each of the dependent claims recites further distinguishing features of particular utility.

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Rejections Under 35 U.S.C. §103

Claims 29, 30, and 40 are rejected under 35 U.S.C. §103(a) as being unpatentable over Nobles et al. As discussed above, Nobles et al. do not teach or suggest an expandable component or seal assembly having an uneven outer surface, as recited in independent Claims 18 and 31, as amended. Claims 29, 30, and 40, which depend from and include all of the limitations of amended Claim 18 or 31, are therefore also patentable as they are not obvious in view of Nobles et al. Furthermore, each of the dependent claims recites further distinguishing features of particular utility.

Conclusion

Applicant respectfully submits that all of the pending claims are patentably distinguishable over the prior art of record. The cited references, either alone or in combination, do not teach or suggest Applicant's claimed invention.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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AMEND

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